K081215

KJAYA MEDICAL, LLC
One Stamford Plaza
263 Tresser Boulevard, 9th Floor, Stamford, CT 06901
Telephone: 203-653-5015. Fax: 203-653-2999

510(k) Summary
(per 21 CFR 807.92)

AUG 26 2008

I. **Applicant**:

KJAYA Medical, LLC
One Stamford Plaza
263 Tresser Boulevard
9th Floor
Stamford, CT 06901
USA

Contact Person: Kovalan Muniandy, Managing Member
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Date prepared: February 26, 2008

II. **Device Name**

Proprietary Name:	Volumina
Common/ Usual Name:	Picture Archiving and Communications System
Classification Name:	System, Image Processing, Radiological
Regulation Number:	892.2050
Product Code:	LLZ
Classification:	2

III. **Predicate Device**

The Volumina is substantially equivalent to the following predicate devices:

- Synapse 3D Visualization Software OBLIQUUS (K061672) from FUJIFILM Medical Systems USA Inc.
- Rtist for Fusion7D, (K033955) from Mirada Solutions, Ltd.

IV. **Indications for Use**

Volumina enables the display of 3D (MIP/MPR) visualization of CT, PET, and MR studies or other DICOM compliant images. Typical users are radiologists, technologists and clinicians. Not for mammographic purposes.

V. **Description of the Device**

Volumina is a Class II software application comprised of a client module and a server module. Volumina is intended to provide a diagnostic quality image to a qualified health care professional to visualize multimodal medical image

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data.

For additional information refer to Section 11. Device Description

VI. Testing

Verification and Validation was conducted according to written protocols and the test outcomes were documented with test reports including pass/fail determination. Verification was monitored and cross referenced in the traceability matrix to ensure all requirements are verified.

Tests were executed under various environments representing actual operating environments and included laptops, desktops, and servers running Microsoft Windows XP, Microsoft Windows XP x64,and Microsoft Windows Server 2003. The various test environments also included connections via a variety of internet and network connections, including DSL, and Cable.

The test data was retrieved from a PACS database containing actual patient Raw Data. Some synthetic data of known dimensions and values was also used for verification and validation.

Due to the close relationship between the Client and Server modules, both were tested simultaneously.

Validation was undertaken to demonstrate that the Volumina Client and Server Modules together consistently fulfill the requirements within the intended use operates as intended under actual operating conditions by accepting the required parameters as input and by returning the expected output, and that the user interface provides a display that is consistent with the data that has been given.

A tabulation of Test Procedures, expected Results and Outcomes and are included in Appendix 16-C Traceability Matrix

For details please see Section 16. Software, Item 7. Verification & Validation Testing.

VII. Safety and Effectiveness

There are no substantial differences between the Volumina defined in this 510(k) submission and the stated predicate devices. They are similar to the technologies that are currently used in other similar medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kjaya Medical, LLC
% Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

AUG 2 6 2008

Re: K081215
Trade/Device Name: Volumina
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 8, 2008
Received: August 11, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K081215

Device Name: Volumina

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081215